In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-191V

(to be published)

KYLE CARDA and SHANNON CARDA, *on behalf of* G.J.C.,	*	
Petitioners,	*	Filed: November 16, 2017
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Decision; Entitlement; Dismissal of Claim; Rotavirus ("RotaTeq") Vaccine; Intussusception.
Respondent.	*	

Robert D. Trzynka, Cutler & Donahoe, LLP, Sioux Falls, SD, for Petitioners.

Sarah C. Duncan, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On March 6, 2014, Kyle and Shannon Carda filed a petition on behalf of their minor child, G.J.C., seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioners allege that G.J.C. suffered from intussusception as a result of receiving two doses of the RotaTeq (rotavirus) vaccine on January 23, 2013, and March 26, 2013, respectively. Petition ("Pet.") (ECF No. 1). An entitlement hearing was held on January 24-25, 2017, and the parties thereafter filed post-hearing briefs. ECF Nos. 84, 88, 89.

[1] This decision will be posted on the United States Court of Federal Claims website, and in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole decision will be available to the public in its current form. *Id.*

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

After considering the record as a whole and the testimony at hearing, I find that Petitioners have failed to carry their burden establishing causation, and therefore **DENY** their request for compensation under the Vaccine Program. Petitioners have not established that G.J.C.'s second RotaTeq dose was temporally close enough in time to his intussusception two months later to be causal, nor have they demonstrated that the first and second doses, whether in concert or separately, could cause a child to experience a series of undiagnosed "transient" or chronic intussusceptions, later culminating in one sufficiently acute to require surgical intervention.

I. Factual Background

Birth and Initial Medical History

G.J.C. was born to the Cardas on November 22, 2012, at 39 1/7 weeks gestation, via spontaneous labor after an "uncomplicated pregnancy." Ex. 2 at 7; Ex. 3. Mrs. Carda's medical records noted, however, that she experienced positive gestational diabetes and decreased fetal movements during the pregnancy. *See, e.g.*, Ex. 1 at 8, 51, 59. G.J.C.'s Apgar scores at birth were 8 at 1 minute and 10 at 5 minutes. Ex. 2 at 7; Ex. 3. On November 29, 2012, G.J.C. was seen for his one-week well-child examination by Dr. Aaron Zylstra at Sanford Children's Clinic in Sioux Falls, South Dakota. Ex. 4 at 2-4. The Cardas voiced no concerns about his behavior or development, and his examination was normal. *Id.* He was noted to be eating three ounces of formula every three hours. *Id.*

G.J.C. returned to Sanford Children's Clinic on January 23, 2013, for his two-month well-child examination. Ex. 4 at 11-14. Again, he was reported to be a happy and healthy baby, and there were no concerns expressed by the Cardas about anything specific. *Id.* G.J.C. had begun to take four to five ounces of formula every three to four hours, and he had multiple wet diapers per day. *Id.* At this visit, G.J.C. received his first doses of the Pentacel,[3] pneumococcal, RotaTeq,[4] and Hepatitis B vaccines. *Id.*

[3] Pentacel is a combination of the Diphtheria-Tetanus-acellular Pertussis, IPV, and Hib vaccines. *Dorland's Illustrated Medical Dictionary* 1406 (32nd ed. 2012) (hereinafter *Dorland's*).

[4] RotaTeq is a live strain attenuated vaccine. *Rotavirus Vaccine, Live (Oral)*, Mayo Clinic, https://www.mayoclinic.org/drugs-supplements/rotavirus-vaccine-live-oral-route/description/drg-20071625 (last visited Oct. 30, 2017). This kind of vaccine contains a living, weakened strain of the disease virus, and is used to elicit a stronger antibody response. *Types of Vaccines*, HHS, https://www.vaccines.gov/basics/types/index html (last visited Oct. 30, 2017). Generally, live strain vaccines create lifelong immunity after one or two doses. *Id.*

Feeding Concerns After First RotaTeq Dose

Mrs. Carda called Sanford Children's Clinic on March 6, 2013 (approximately six weeks after administration of the first RotaTeq dose), to report her concerns that G.J.C. was now eating less formula (three to four ounces instead of five), although he was still having "plenty" of wet diapers. Ex. 4 at 22. The nurse explained that there was no reason for concern at this point unless his intake continued to decrease. *Id.* A week later, on March 15, 2013, Mrs. Carda called again because she had switched G.J.C.'s formula to a soy brand, and he was now experiencing harder stools and constipation. *Id.* at 27. She was informed that this was typical when switching from milk to soy, and that his stools should improve. *Id.* The nurse also informed her that if he arched his back, ceased bowel movements, or developed abdominal distension, she should follow up with the hospital. *Id.* The records from this period make no reference to any extreme or notable reaction to the vaccines G.J.C. had received on January 23rd, although (as discussed below) the Cardas maintain that they began to see concerning changes in G.J.C. within this two-month period.

Thereafter, G.J.C. presented for his four-month well-child check-up on March 26, 2013. Ex. 4 at 32-33. His parents now reported that he had been a frustrating eater over the last month and would seem to fuss and arch his back during feedings. *Id.* However, they also noted he had not been spitting up too much and was still a happy baby. *Id.* G.J.C. had multiple wet diapers and daily hard stools. *Id.* The notes reveal that G.J.C.'s development for most areas was on schedule. *Id.* at 35-36. At this visit, he was prescribed an antacid (Prilosec[5]) for Gastroesophageal Reflux Disease ("GERD"), to be taken 20 to 30 minutes prior to feeding. *Id.* at 47. G.J.C. also received his second dose of the Pentacel, pneumococcal, and RotaTeq vaccines. *Id.* at 33.

Medical Problems After Second RotaTeq Dose

Almost three weeks after administration of the second RotaTeq dose, Mrs. Carda called Sanford Children's Center on April 15, 2013, to report that G.J.C. was exhibiting a "concerning" decreased appetite. Ex. 4 at 43-52. She specifically noted that he would refuse his bottle, and that he ate only eight to ten ounces of formula the previous day. *Id.* at 44. He was allegedly having fewer wet diapers, although he was not losing any weight. *Id.* Dr. Zylstra noted that reflux issues similar to G.J.C.'s were likely attributable to an infant not eating much. *Id.* at 43. He suggested that they change G.J.C.'s anti-reflux medication and formula, as well as perform an upper gastrointestinal exam ("UGI") to rule out any more serious but unidentified problems. *Id.* Mrs. Carda agreed to schedule a UGI the following day, and asked to bring G.J.C. in for an examination as well. *Id.*

[5] Prilosec is a trademark name for a preparation of omeprazole, which is a proton pump inhibitor used to treat gastroesophageal reflux disease and administered orally. *Dorland's* at 1319, 1514.

The examination noted that G.J.C. had a sore on his left lower lip. Ex. 4 at 50. Although he appeared to be gaining weight appropriately, Mrs. Carda reported that he had been experiencing constipation for four months that had worsened since switching to a soy formula. *Id.* G.J.C. was diagnosed with GERD and herpangina.[6] *Id.* The assessment plan noted that he should continue to take Prilosec daily to treat his GERD symptoms, and also that Mrs. Carda should add Karo syrup to his bottles in order to relieve constipation. *Id.* Dr. Rosanne Bosch also recommended that G.J.C. stop receiving soy formula due to a mild rash and his constipation. *Id.* The UGI results were obtained a day later, on April 17, 2013, and confirmed the existence of reflux but identified no anatomic problems that might be contributing to G.J.C.'s GERD. *Id.* at 48; Ex. 6 at 68.

Intussusception and Surgical Intervention

A little over a month later, on May 22, 2013, Mrs. Carda contacted Sanford Children's Clinic to inquire about G.J.C.'s lethargy and inability to eat or keep anything down. Ex. 4 at 63. She now reported that he was vomiting and dehydrated, and sought to bring him in to be evaluated by Dr. Zylstra. *Id.* at 63, 69. The medical report from this visit noted that per Mr. and Mrs. Carda's recollection, G.J.C. had evinced a decreased appetite the previous day that gradually worsened. *Id.* The Cardas also reported that he had experienced increased reflux issues over the past month. *Id.* Mr. Carda specifically stated that G.J.C. looked like he was experiencing heartburn or reflux after he ate, and that he would vomit within one hour after eating. *Id.* They also reported, however, that since switching G.J.C.'s formula to Gentlease, his constipation had greatly improved. *Id.* Dr. Zylstra observed that G.J.C. looked well and well-hydrated, despite the report of decreased "UOP" (urine output). *Id.* at 69. He opined that there might be an acute viral process occurring in addition to G.J.C.'s reflux, and correspondingly increased the Prilosec dosage. *Id.* G.J.C. was then sent home. *Id.*

Later in the afternoon of May 22, 2013, according to Mrs. Carda, G.J.C. began to look even worse, and Mrs. Carda's sister convinced her to bring him back to the hospital. Tr. at 338. Upon arrival, G.J.C. was determined to be dehydrated and given an IV with fluids. Ex. 6 at 81. Mrs. Carda testified that she next saw G.J.C. "vomiting feces and bile" (Tr. at 109-11), although the medical records from that visit state that Mrs. Carda produced to treaters a blanket with "numerous areas of brownish-green spit-up" that were not very big. Ex. 6 at 117. Those same contemporaneous medical records do not reflect any independent treater observing feces stains of the kind reported.

[6] Herpangina is an acute infectious disease caused by either group A or B coxsackievirus or echoviruses, chiefly affecting young children in the summer. *Dorland's* at 852. It is characterized by vesiculoulcerative lesions on the mucous membranes of the throat, plus dysphagia, vomiting, and fever. *Id.*

The Sanford treaters performed an x-ray revealing a bowel obstruction. Ex. 6 at 84. G.J.C. then underwent an abdominal ultrasound to ascertain the cause of the obstruction. *Id.* at 81. The ultrasound revealed right targetoid lesions, indicating that G.J.C. was experiencing an intussusception (meaning intestinal obstruction) in his small bowel. *Id.* at 85.

In order to treat the intussusception, an air enema reduction was performed, but it was only partially successful. Ex. 6 at 84, 151. Due to the incomplete reduction, on May 23, 2013, G.J.C. underwent a laparotomy,[7] followed by an open reduction with manual manipulation. Ex. 6 at 78-79, 84-85. During this surgery, G.J.C. also received an appendectomy. *Id.* at 228. The procedure was ultimately successful, and G.J.C. recovered well, though he had a slow return of bowel function. *Id.* There is no indication from the procedure notes that the surgeon removed any portion of G.J.C.'s small bowel. *See id.*

Subsequent Related Sequelae

On May 28, 2013, G.J.C. returned to Sanford Medical Center due to continued pain and complaints from the Cardas that he was not eating or sleeping well. Ex. 6 at 85, 89. Abdominal x-rays revealed the presence of a large amount of free air, and G.J.C. had abdominal distention and lethargy. *Id.* at 39, 143-48. Dr. Jon Ryckman recommended another exploratory laparotomy with possible bowel resection and stoma creation. *Id.* at 85, 89. During this surgery, two small perforations were identified in the small bowel: one underneath the incision from the previous surgery, and one iatrogenic serosal tear. *Id.* These were repaired, and it was noted that G.J.C.'s bowel otherwise appeared fine and healthy. *Id.* G.J.C. was discharged on June 2, 2013, after recovering from his surgeries. *Id.* at 228.

From June 4-6, 2013, G.J.C. was again admitted to Sanford Medical Center for poor feeding, irritability, and a possible bowel obstruction. Ex. 6 at 1053-57. He was diagnosed with dehydration and narcotic withdrawal, but no recurrent intussusception was noted. *Id.*

G.J.C.'s next significant medical visit was to Sanford Children's Specialty Clinic to Dr. Jones-Sapienza on June 14, 2013, for surgical follow-up and routine post-operative care. Ex. 5 at 1. He was determined to be fine and tolerating his diet, and was voiding and stooling without difficulties. *Id.* Dr. Jones-Sapienza did inform the Cardas of G.J.C.'s lifelong possibility of additional adhesive bowel obstructions, however, advising them to continue to monitor him for abdominal distention or bilious emesis. *Id.*

[7] A laparotomy is defined as a surgical incision into the abdominal cavity. *Dorland's* at 1005.

G.J.C. next had a six-month well-child visit with Dr. Zylstra on June 17, 2013, at which time he was deemed to be recovering well despite some slight complications after surgery. Ex. 4 at 81. His parents reported that G.J.C. was taking four to six ounces of Gentlease formula every four to five hours. *Id.* Mrs. Carda also called back the next day, June 18th, due to concern that G.J.C. was eating less after surgery, though she did not think he looked ill or uncomfortable. Ex. 5 at 9. Dr. Jones suggested that she continue to watch him for any further worrisome signs and to bring him to the emergency department if his symptoms worsened. *Id.* The medical record contains no additional materials relevant to G.J.C.'s claim after this date.

II. Fact Witness Testimony

Both Kyle and Shannon Carda testified in person at the entitlement hearing, and also provided witness affidavits. Tr. at 5-126, 321-54; ECF No. 5.

A. Shannon Carda

Mrs. Carda confirmed most of what is reflected in the medical records, specifically testifying to the fact that G.J.C. was a healthy baby prior to his RotaTeq vaccinations and that he had never experienced problems with pain or spitting up until after vaccination. Tr. at 7-8. Importantly, however, and in contrast to the records, Mrs. Carda testified that G.J.C. began to experience a reaction in the days and weeks after his first RotaTeq vaccination on January 23rd, characterized by "forceful vomiting," eating less, arching his back, and tensing up while he was playing, which worsened after his second vaccination on March 26th. *Id.* at 9-10, 14-15. She also reported that G.J.C. became more and more lethargic, and would wake up screaming in pain during the night. *Id.* at 19.

Mrs. Carda further testified that when G.J.C. was admitted to the hospital on May 22, 2013 (Ex. 6 at 83), he was so dehydrated that it took several nurses multiple attempts to place the IV. Tr. at 23. She also asserted, as noted above, that during this visit he was vomiting feces and bile. *Id.* at 109. When challenged as to why the medical records did not reflect her contention (and in fact contradict the claim that bile or feces were observed in G.J.C.'s vomit), Mrs. Carda speculated that he may have done this after the treater's observation (but the occurrence was not formally recorded). *Id*. at 111.

A general subject of Mrs. Carda's cross-examination was the disparity between her recollection of events and the actual medical records. Mrs. Carda repeatedly stated that she could not explain why the records did not reflect her current recollections, and expressed frustration that treaters had not recorded the facts as she recalled them. *See, e.g.*, Tr. at 45, 47-48, 56 ("[B]ut this isn't me writing this down. This is what the nurse and the doctors have put into the medical records.

So what I say and how they describe it could be completely different."), 108. She asserted that she had expressed her concerns about G.J.C. in detail to his medical providers as they were occurring, but that the treaters may have failed to take her seriously or to have accurately recorded her observations. *Id.* at 115-17. At the same time, she proposed that she may not have adequately informed treaters of what she was observing with G.J.C. because her husband, friends, and even the medical professionals kept assuring her that these were normal symptoms for a baby and that he was perfectly healthy. *Id.* at 40-42, 84.

Mrs. Carda otherwise testified that after the second revision surgery, G.J.C. returned to normal and had no further issues feeding, and has since not required Prilosec or GERD medication. Tr. at 25-27.

B. Kyle Carda

Mr. Carda's testimony echoed the content of his wife's testimony. Mr. Carda noted that he was very involved in G.J.C.'s care, and that the Cardas often scheduled G.J.C.'s appointments around Mr. Carda's work schedule. Tr. at 322-23. However, he was less able to recall dates and details, deferring to his wife's testimony and recollection. *Id.* at 333. Like Mrs. Carda, Mr. Carda also maintained that the contemporaneous medical records did not accurately reflect G.J.C's symptoms, asserting that treaters had not taken the Cardas seriously, and/or had assumed that G.J.C.'s symptoms were attributable to GERD. *Id.* at 336, 346. Mr. Carda also testified that Dr. Jon Rykman, the surgeon who performed G.J.C.'s reduction, was the individual who first explained to them the possibility that G.J.C.'s intussusception could have been related to his RotaTeq vaccination (although it does not appear that this treater was informed *when* G.J.C. had received either RotaTeq dose). *Id*. at 352.

III. Expert Testimony

Both sides offered two experts at hearing, as well as their written expert reports. The opinions and testimony of the relevant experts are set forth below.

A. *Dr. John Santoro*

The first of Petitioners' two experts, John Santoro, M.D., filed two written reports and testified via videoconference at hearing. *See* Expert Report, dated Dec. 15, 2014, filed as Pet.'s Ex. D (ECF No. 15-1) ("First Santoro Rep."); Expert Report, dated May 12, 2015, filed as Pet.'s Ex. M (ECF No. 23-1) ("Second Santoro Rep."). Dr. Santoro opined that the RotaTeq vaccinations G.J.C. received caused or significantly contributed to his intussusceptions.

Dr. Santoro currently works at Atlantic Gastroenterology Associates, P.A. as a doctor of osteopathic medicine and gastroenterology. *See* Santoro CV (ECF No. 68-1) at 1; Tr. at 131. He obtained his Bachelor of Arts in biology from LaSalle College in 1973, and his M.D. from Philadelphia College of Osteopathic Medicine in 1978. Santoro CV at 1. He completed an internship at John F. Kennedy Memorial Hospital from 1978-79, and performed his residency in internal medicine at the University of Medicine and Dentistry at the NJ School of Osteopathic Medicine from 1979-81. *Id.* Dr. Santoro also completed a fellowship in gastroenterology at the University of Medicine and Dentistry NJ School of Osteopathic Medicine from 1981-83. *Id.* at 2. He is board certified in internal medicine and gastroenterology. *Id.* Additionally, he serves as a clinical associate professor of medicine at Rowan University School of Osteopathic Medicine. *Id.* at 3.

As a gastroenterologist, Dr. Santoro testified that he spends 95 percent of his time seeing patients, with the remaining five percent dedicated to clinical research and teaching. Tr. at 131. While part of his rotation involved pediatric gastroenterology, he more commonly sees patients above the age of 11, and does not treat infants and younger children, although he has experience treating children with GERD and has also experienced two patients with acute intussusception. *Id.* at 150-53. Dr. Santoro has published multiple articles in gastroenterology journals. *Id.* at 4-5. He is not, however, an immunologist.

At hearing, Dr. Santoro explained intussusception to be the telescoping of the intestine in upon itself, creating a bowel obstruction. Tr. at 134. An ileocolic intussusception is, he opined, the proper classification for G.J.C.'s intussusception. *Id.* at 198. As Dr. Santoro explained, the ileum is the last section of the small bowel, and thus an ileocolic intussusception occurs at that location, when the ileum inverts into the large bowel. *Id.* at 199. Dr. Santoro did not distinguish between a small bowel intussusception and ileocolic intussusception. *Id.* at 197.

Although Dr. Santoro noted that the Petitioners' other expert, Dr. Yehuda Shoenfeld, would testify as to the immunologic mechanisms that could theoretically result in a vaccine-induced intussusception, he nevertheless covered the topic somewhat in his testimony. Dr. Santoro maintained that the RotaTeq vaccine was capable of producing a lymphadenopathy[8] in the ileum, causing a small-bowel intussusception akin to what G.J.C. experienced. Tr. at 145. In effect, an inflammatory infection or disturbance could cause edema, or swelling, in the bowel wall, later resulting in G.J.C.'s symptoms and eventual acute intussusception. *Id.* He did not find it notable that G.J.C.'s intussusception followed his second rather than first dose of the vaccine, opining that the second dose can be more "intense" due to an anamnestic (immunologic memory) response. *Id.* In his opinion, there was no other possible explanation for what had occurred. *Id.* at 146.

[8] Lymphadenopathy is defined as a disease of the lymph nodes, usually coupled with swelling. *Dorland's* at 1083.

To support his causation theory, Dr. Santoro recalled the historical link between an earlier version of the rotavirus vaccine (Rotashield) and intussusception. First Santoro Rep. at 5. Rotashield was eventually pulled from the market and is no longer administered to infants. *Id.* Dr. Santoro also explained that there have been hundreds of "confirmed" intussusception events following administration of the RotaTeq vaccine reported to VAERS.[9] *Id.* at 6.

Dr. Santoro also relied on several articles suggesting a link between other versions of the vaccine and intussusception. For instance, a study performed in Mexico found that a different rotavirus vaccine (RV-1) was associated with a short-term risk of intussusception in roughly one of every 51,000 to 68,000 vaccinated infants. First Santoro Rep. at 5, *citing* Patel et al., *Intussusception Risk and Health Benefits of Rotavirus Vaccination in Mexico and Brazil*, 364 New Eng. J. Med. 2283, 2283 (2011), filed as Ex. 12-1 (ECF No. 70-1). He similarly offered an article studying intussusception risk after receipt of the RV-1 monovalent rotavirus vaccine. First Santoro Rep. at 5; *see also* Weintraub et al., *Risk of Intussusception after Monovalent Rotavirus Vaccination*, 370 New England J. Med. 513, 513-19 (2014), filed as Ex. 12-14 (ECF No. 70-14)("Weintraub"). Weintraub observed a significant increase in the rate of intussusception following vaccination; after two doses of the vaccine, the estimated risk was noted as 5.3 per 100,000 infants. First Santoro Rep. at 5. Another piece of literature considered the connection between intussusception and RV-5 in the United States. *Id.* at 6-7, *citing* Yih et al., *Intussusception Risk after Rotavirus Vaccination in U.S. Infants*, 370 New Eng. J. Med. 503, 503-13 (2014), filed as Ex. 12-13 (ECF No. 70-13) ("Yih"). Yih concluded that approximately 1.5 cases of intussusception occurred per 100,000 recipients of the first dose.

Beyond proposing that RotaTeq could cause an intussusception, Dr. Santoro grappled with the medical record in an effort to show how, in G.J.C's case, his proposed theory had actually unfolded.[10] In particular, he attempted to reconcile his theory with the facts that (a) K.J.C. never experienced an intussusception requiring surgical intervention after his January 23rd receipt of the first RotaTeq dose, and (b) approximately eight weeks passed from G.J.C.'s second RotaTeq vaccination and his acute intussusception. To do so, Dr. Santoro attempted to delineate a form of intussusception separate from its commonly-understood acute form – a chronic, or transient,

[9] The Vaccine Adverse Event Reporting System ("VAERS") is a national warning system designed to detect safety problems in U.S.-licensed vaccines. *See About VAERS*, VAERS, https://vaers hhs.gov/about html (last visited Sept. 26, 2017). It is managed by both the CDC and the FDA. VAERS monitors and analyzes reports of vaccine related injuries and side effects from both healthcare professionals and individuals.

[10] Significantly, at trial Dr. Santoro had difficulty explaining the evidentiary bases for certain fact statements in his written reports about G.J.C.'s medical history. When confronted with discrepancies between his recitation of the medical history and the actual record, he blamed them on the fact that the reports had been written years before the hearing. *See, e.g.*, Tr. at 159-60. Further, Dr. Santoro admitted he had incorrectly stated in his report that G.J.C.'s intussusception surgery included a bowel resection, when in fact the records establish that *no* portion of G.J.C.'s colon was removed in surgically correcting the intussusception. *Id.* at 166-67.

intussusception. Tr. at 134-35. In his opinion, G.J.C. had been experiencing less severe forms of intussusception that were ongoing, or chronic, from the time of his first RotaTeq dose – not severe enough to require invasive surgical attention but nevertheless related to the vaccine, and culminating in the May 23, 2013, surgery, when the problem had become sufficiently acute. *Id.* at 136, 180.

For support, Dr. Santoro relied on an article that studied transient/chronic intussusceptions observing symptoms similar to what G.J.C. is said to have experienced, such as abdominal pain, vomiting, and abdominal distension. Tr. at 135-36; *see* Mateen et al., *Transient Small Bowel Intussusceptions: Ultrasound Findings and Clinical Significance*, 31 Abdominal Imaging 410, 410-16 (2006), filed as Ex. 12-27 (ECF No. 70-27) ("Mateen"). Mateen was a review study noting instances in which spontaneously-resolving small bowel intussusceptions were incidentally discovered in children by medical treaters, in the course of treating some other abdominal complaint. Mateen at 410. All resolved without the need for surgical intervention, but none recurred thereafter, and in no instances were treaters able to identify the pathologic source of the detected resolved intussusception. *Id.* at 413-14. Mateen's authors concluded that these one-time, transient intussusceptions had "no clinical significance as they reduce spontaneously and their presence warrants only conservative observation." *Id.* at 416.

Dr. Santoro also referenced a case study of a child who presented to medical treaters with distinct episodes of pain. Tr. at 137-38; *see* Steffen et al., *Intermittent Intussusception as a Cause of Abdominal Pain in Children*, 118 Am. Gastroenterological Ass'n A1073 (2000), filed as Ex. 12-22 (ECF No. 70-22)("Steffen"). As discussed in Steffen, an ultrasound ultimately revealed the child had likely experienced an undiagnosed intussusception, suggesting to Dr. Santoro that instances of ongoing abdominal pain or related symptoms might reflect the existence of some ongoing transient intussusception. Tr. at 138. While Dr. Santoro allowed for the fact that such chronic intussusception is rare, he argued it remained possible, relying on literature from 1976 that proposed that chronic intussusception was a plausible explanation for children experiencing persistent, otherwise-unexplained abdominal problems. Second Santoro Rep. at 2, *citing* Rees & Lari, *Chronic Intussusception in Children*, 63 Br. J. Surgery 33, 33-35 (1976), filed as Resp't's Ex. D.7 (ECF No. 65-7).

In so opining, Dr. Santoro attacked the notion that G.J.C.'s documented GI-related symptoms in the months prior to his May 23rd surgery reflected feeding problems or GERD. Second Santoro Rep. at 1-2; Tr. at 191-92. GERD, Dr. Santoro opined, often presents in infants as fussiness at feeding time, with crying and/or regurgitating after feeding. Tr. at 188-89. GERD would not feature arching of the back. *Id.* at 189. But in his view, G.J.C.'s presentation was acute in precisely this manner, characterized as well by significant abdominal pain and other severe symptoms evident (at least based on witness testimony rather than records) from around the time of the first vaccine dose. *Id.* at 179-81, 186-87. At bottom, although G.J.C.'s treaters might have

relied on medical common sense in assuming that his symptoms were not unusual, in this case they reflected something far less often encountered. *Id.* at 142 ("[w]hen you hear hoof beats, think of horses, but often those hoof beats are really zebras, and in this case, it wasn't a horse; it was a zebra").

Dr. Santoro also proposed that the unsuccessful treatment of G.J.C.'s GERD further excluded it as an explanation. Once pediatric treaters determined that GERD was interfering with an infant's feeding, they would commonly prescribe medications to address the symptoms rapidly (perhaps as quickly as within a day). *Id.* at 189-90. But Prilosec never relieved G.J.C.'s symptoms. Tr. at 146. The Prilosec treatment should have been far more efficacious in resolving his symptoms had GERD been their source. *Id.* at 147.

Dr. Santoro endeavored to explain the long passages of time between G.J.C.'s two RotaTeq vaccinations and his ultimate surgical intervention. He maintained that G.J.C. experienced his first transient/chronic small-bowel intussusception after the initial RotaTeq dose, with an additional intussusception after the second dose, culminating in the acute intussusception in May. Tr. at 174-75, 184. For support that this was medically reasonable, he largely relied on VAERS database information. Ex. 12-17 at 4. And he rejected the assumption that G.J.C.'s actual intussusception symptoms did not begin until May 21, 2013, characterizing the earlier symptoms displayed after the first dose as proof of transient intussusception. Tr. at 179, 184.

In proposing this timeframe to be medically acceptable, Dr. Santoro acknowledged that it was largely understood in the medical community that acute intussusceptions following rotavirus vaccinations would be expected to occur within two weeks of receiving the first dose -- something that unquestionably did not occur in this case. First Santoro Rep. at 9. Dr. Santoro nevertheless maintained that a vaccine-caused intussusception could still occur after the second or third dose as well. Second Santoro Rep. at 3. When confronted with many articles that placed the highest risk for intussusception three to seven days following vaccination within a 21-day risk period, Dr. Santoro argued that the timeframe was arbitrary, and noted the existence of other reports of cases of intussusception that occurred 78 days following vaccination. Tr. at 173-74, *citing* Haber et al., *Intussusception After Rotavirus Vaccine Reported to US VAERS, 2006-2012*, 131 Pediatrics 1042 (2013), filed as Ex. 12-17 (ECF No. 70-17). The fact that some cases occurred in a cluster following the first vaccination did not in his opinion eliminate the possibility of later-occurring post-vaccination cases. *Id.* at 174.

B. *Dr. Yehuda Shoenfeld*

Petitioners' second expert was Dr. Shoenfeld, who filed one expert report and also testified at hearing. *See* Expert Report, dated Oct. 25, 2015, filed as Pet.'s Ex. A (ECF No. 28-1) ("Shoenfeld Rep."). Like Dr. Santoro, Dr. Shoenfeld opined that there was a causal link between

G.J.C.'s vaccinations and his intussusception, based upon the concept of a transient or chronic intussusception later culminating in one sufficiently acute to require surgical intervention.

Dr. Shoenfeld is currently the head of the Center for Autoimmune Diseases, which he founded at the Sheba Medical Center in Israel. Shoenfeld CV (ECF No. 54-2). He is also the incumbent of the Laura Schwarz-Kipp Chair for Research of Autoimmune Diseases at Tel Aviv University. *Id.* His experience focuses on autoimmune and rheumatic diseases, and he has published many peer-reviewed papers in journals and books on these topics. *Id.* He is on the editorial board of 32 journals in the field of autoimmunity. *Id.* Unlike Dr. Santoro, Dr. Shoenfeld lacks specialized expertise in gastroenterology and has no identified history of treating or diagnosing pediatric patients with any such illnesses. Tr. at 242-43, 246.

Dr. Shoenfeld's expert report began with a summary of the medical records, followed by his proposed causation theory. *See generally* Shoenfeld Rep. Dr. Shoenfeld maintained that there is a relationship between the RotaTeq vaccine and intussusception demonstrated in the literature. *Id.* at 6. He examined data on the RV-1 and RV-5 formulations of rotavirus, and noted that the VAERS database received 108 confirmed intussusception reports following these vaccines from February 2008 to December 2014.

Dr. Shoenfeld also relied on two papers also cited by Dr. Santoro that he proposed established a causal relationship. Shoenfeld Rep. at 7; *see also* Yih; Weintraub. The Yih study found an increased risk of intussusception following vaccination with RotaTeq and Rotarix in the United States. Shoenfeld Rep. at 7. That study involved only vaccinated children, and found that excess cases of intussusception following the first dose of RV-5 was significantly elevated in the 21-day risk window. *Id.* Yih did not, however, find a significant increase in risk after doses two or three for RV-5, although there was a significant risk after dose two of RV-1. *Id.* Thus, Yih concluded that RV-5 was associated with 1.5 excess cases of intussusception per 100,000 recipients of the *first* dose. *Id.* The Weintraub study Dr. Shoenfeld referenced found that in a vaccine post-licensure study of more than 200,000 doses of the monovalent rotavirus vaccine, there was a significant increase in the rate of intussusception following vaccination. *Id.* at 8. The risk following rotavirus vaccination with RV-5 is increased for three to seven days - mainly after the first dose but only marginally after the second and third doses. *Id.* at 9. Thus, even though most intussusceptions had occurred within two weeks following vaccination and usually after the first dose, Dr. Shoenfeld opined that it could still occur after the second or third dose. *Id.*[11]

[11] Dr. Shoenfeld also included a section in his report that noted that RotaTeq was withdrawn from the market. Shoenfeld Rep. at 9. However, this is incorrect - as the report states, it was the RotaShield vaccine that was found to be associated with an increased risk of intussusception and its use was discontinued. *Id.*

Based on the literature and studies, Dr. Shoenfeld maintained that there was a plausible biologic mechanism linking the vaccination to G.J.C.'s intussusception. Shoenfeld Rep. at 9. As he explained, the vaccine would cause the upregulation of cytokines with the capacity to inflame and stimulate the smooth muscles of the bowel, resulting in increased movement or peristalsis. Tr. at 230-32. This inflammation would then cause edema or swelling, which could later produce an acute intussusception. *Id.* at 223-24. Dr. Shoenfeld expressly acknowledged, however, that he does not understand intussusception to be an autoimmune illness (and therefore did not offer an opinion in this case that G.J.C.'s condition was mediated by an autoimmune process). *Id.* at 245.

To explain the timeframe in which the RotaTeq vaccine purportedly injured G.J.C. over the four-month period between first dose and surgical intervention, Dr. Shoenfeld relied on the concept of "challenge-rechallenge" often raised in Vaccine Program cases. Tr. at 221-22, 228.[12] In effect, G.J.C.'s immune system, primed for a response to RotaTeq after receiving the first dose in January 2013, experienced a more robust response after the March dose, logically explaining the eventually acute intussusception experienced later that spring. *Id.* at 240. Dr. Shoenfeld did not, however, explain how the apparent lack of undocumented symptoms in the first few weeks after the second dose corroborated his opinion (or why the acute intussusception took a total of over six weeks to manifest after the March 26th second dose).

In Dr. Shoenfeld's reading of the medical record, G.J.C.'s symptoms began within days after the first vaccination and then progressed after the second dose. Based on the above literature that he read as establishing a plausible mechanism, Dr. Shoenfeld opined that G.J.C.'s intussusception was directly caused by the two RotaTeq vaccinations he received. Shoenfeld Rep. at 10. Relying on literature that was based upon VAERS data, Dr. Shoenfeld proposed that up to 80 days could pass from a RotaTeq dose to an acute intussusception and still be medically acceptable. Tr. at 294. Indeed – Dr. Shoenfeld allowed for four or even five months to pass between vaccine receipt and intussusception and still be a medically reliable timeframe. *Id.* at 314.

C. *Dr. Neal Halsey*

Respondent submitted two reports from Dr. Halsey. *See* Expert Report, dated April 7, 2015 (filed as Resp't's Ex. A) (ECF No. 18-1) ("Halsey Rep."); Supplemental Expert Report, dated July 18, 2016 (filed as Resp't's Ex. F) (ECF No. 43-1) ("Second Halsey Rep.").

[12] Challenge-rechallenge is "a paradigm for exploring whether one substance caused an adverse reaction. Under this model, an individual who has had an adverse reaction to the initial vaccine dose (the challenge event) suffers a worsening of symptoms after a second or third injection (the rechallenge event.)" *Viscontini v. Sec'y of Health & Human Servs.*, No. 98-619V, 2011 WL 5842577, at *22 (Fed. Cl. Spec. Mstr. Oct. 21, 2011) (quoting *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 603 (2010) (quotations omitted)), *mot. for review den'd,* 103 Fed. Cl. 600 (2012).

Dr. Halsey is currently a professor in the Departments of International Health and Pediatrics at Johns Hopkins University. Halsey CV, filed as Resp't's Ex. B (ECF No. 20). In addition, he serves as the director for the Institute for Vaccine Safety. *Id.* He received his undergraduate and medical degrees from the University of Wisconsin. *Id.* He completed his pediatric residency at the University of Colorado, and also performed an NIH residency in pediatric infectious diseases. *Id.* He further served as an Academic Intelligence Officer in the Centers for Disease Control and Prevention's ("CDC") Immunization Division. *Id.* Dr. Halsey is board certified in pediatrics and pediatric infectious diseases. Although Dr. Halsey no longer sees patients regularly, he testified that he has treated many thousands of children with the rotavirus illness. Tr. at 364. He further testified that he has diagnosed six or seven children with intussusception, all under the age of two. *Id.* at 365.

Based on his review of G.J.C.'s medical records, Dr. Halsey maintained that the G.J.C.'s intussusception was not the result of the rotavirus vaccine. Tr. at 393; Second Halsey Rep. at 3. While Dr. Halsey agreed that RotaTeq can cause intussusception, he opined that any increased risk of acute intussusception associated with the vaccine occurs almost exclusively within the first 21 days after vaccination. Tr. at 392. G.J.C., however, first presented with symptoms of intussusception during the earlier hours of May 22, 2013, 57 days after his *second* vaccination. *Id.* at 394-95. Dr. Halsey proposed intussusception beginning in such a timeframe was not medically or scientifically plausible because "the virus doesn't cause persistent changes in the gut that would lead to intussusception at a later time." *Id.* at 393, 405. Rather, RotaTeq contains live strains of the rotavirus, and their peak period of replication is a shorter time, relatively speaking, than allowed for by Petitioners' theory. *Id.* at 400-01.

For the same reason, Dr. Halsey rejected Petitioners' argument (advanced by Dr. Shoenfeld) that the concept of challenge-rechallenge could explain why G.J.C. experienced a more severe reaction to RotaTeq after receipt of the second dose. Tr. at 408-09. In Dr. Halsey's view, although a live virus vaccine like RotaTeq would be administered twice to ensure *some* immune response, the response to a live virus vaccine would inherently be less robust in subsequent doses (*Id.* at 409) – whereas with inactive or killed-virus vaccines, the second dose is more likely to produce a more robust immunologic response (*Id.* at 408). Accordingly, Dr. Halsey felt that Dr. Shoenfeld was misapplying challenge-rechallenge to the kind of vaccine at issue in this case.

To support his opinion, Dr. Halsey relied on three papers establishing the risk interval of intussusception following rotavirus vaccination. Dr. Halsey first offered an article concluding that the increased risk of intussusception was highest between three to fourteen days following the RotaShield vaccine, based on a case-control study comparing 429 infants diagnosed with intussusception with 1,763 healthy infants in 19 states. *See* Murphy et al., *Intussusception Among Infants Given an Oral Rotavirus Vaccine*, 344 New Eng. J. Med. 564 (2001), filed as Resp't's Ex. A-12 (ECF No. 63-2) ("Murphy"); Tr. at 397-98. Dr. Halsey acknowledged that the Murphy paper

discussed intussusception risk following the RotaShield vaccine, which is no longer in use, rather than the RotaTeq vaccine at issue in this case. Tr. at 397. However, Dr. Halsey explained that he relies on the Murphy paper because it is the first study to document the time interval of increased risk after any form of the rotavirus vaccine. *Id.*

Dr. Halsey next referred to the Yih article (also filed by Petitioners and cited by their experts), which he deemed the first article discussing an increased risk of intussusception following the RotaTeq vaccine in U.S. infants. *See* Yih (filed by Respondent as Ex. D-8 (ECF No. 65-8)). Using both a self-controlled risk interval and cohort design,[13] Yih concluded that intussusception symptoms following the rotavirus (RV5 and RV1) vaccine presented within seven to twenty-one days after vaccination. *Id.* at 506; Tr. at 403. But Yih found no significant risk of intussusception following a second or third dose. Yih at 506; Tr. at 407. Dr. Halsey also relied on an article similarly observing that the main risk of intussusception fell in the days immediately after the first dose. Halsey Rep. at 7; *see* Haber et al., *Intussusception After Monovalent Rotavirus Vaccine—United States, Vaccine Adverse Event Reporting System (VAERS), 2008-2016*, 33 Elsevier 4873, 4873 (2015), filed as Resp't's Ex. D-10 (ECF No. 65-10) ("Haber"). Based on such studies, Dr. Halsey opined that there is no meaningfully increased risk for intussusception beyond 21 days after receipt of the first initial dose of rotavirus vaccine. Tr. at 404; Halsey Rep. at 6; Second Halsey Rep. at 1.

Dr. Halsey also dismissed Petitioners' argument that G.J.C.'s feeding problems, or GERD symptoms, were consistent with chronic/transient intussusception. Dr. Halsey categorized GERD as a common pediatric diagnosis involving spitting up, vomiting, irritability, feeding refusal, and poor weight gain. Tr. at 390; Halsey Rep. at 5. According to Dr. Halsey, GERD symptoms can also include regurgitation, arching of the back, and pain associated with acidic reflux in the esophagus. Tr. at 390-91. G.J.C.'s symptoms, including reflux, regurgitation, and esophageal pain and discomfort, were not consistent with intussusception. *Id.*; Halsey Rep. at 5. Rather, G.J.C. first presented with the kind of severe symptoms associated with intussusception no sooner than May 22, 2013. Tr. at 393-94.

In response to Petitioners' chronic/transient intussusception theory, Dr. Halsey opined that intussusception is understood in the medical community to be primarily an acute, life-threatening illness as opposed to an insidious chronic health problem. Halsey Rep. at 5. Dr. Halsey acknowledged that there is medical literature in existence discussing the possibility of minor,

[13] A cohort study is a type of epidemiologic study where groups of individuals can be identified as exposed to the agent or agents hypothesized to have caused a disease or other outcome. *Reference Manual on Scientific Evidence* 621 (3rd ed. 2011). A cohort method involves observing populations over a certain number of years in order to generate reliable scientific evidence showing if an exposed group is likely to develop a disease. *Id.* Cohort studies generally require a large population study over a long period of years. *Id.*

transient invagination of the small bowel that resolves without medical intervention (and that may not always be discovered), but maintained that this kind of minor invagination would not be expected or understood to evolve into an acute intussusception. Tr. at 437-38; 447. Indeed, according to Dr. Halsey, an invagination is a normal phenomenon that occurs in *all* people involving no pathologic mechanism. *Id.* at 445; Halsey Rep. at 5. Dr. Halsey testified that no studies analyzing the relationship between "temporary" invagination and the rotavirus vaccine exist, making it impossible to opine as to whether the rotavirus vaccine could even cause a "temporary" invagination. *Id.* at 448. Ultimately, Dr. Halsey refused to accept the theory as medically reliable, stating that he is not convinced "transient intussusception" is a real phenomenon despite its brief mention in some of the literature filed by Petitioners. *Id.* at 438, 453.[14]

D. *Dr. Chris Liacouras*

Dr. Liacouras served as Respondent's second expert. *See* Expert Report, dated Jan. 7, 2016 (filed as Resp't's Ex. D) (ECF No. 31-1) ("Liacouras Rep."). He is currently a professor of pediatrics and pediatric gastroenterology and nutrition at the Perelman School of Medicine at the University of Pennsylvania, Children's Hospital of Philadelphia. Liacouras CV, filed as Resp't's Ex. E (ECF No. 31); Tr. at 506. Dr. Liacouras received his undergraduate degree from Johns Hopkins and his medical degree from Harvard Medical School. Tr. at 501. During medical school, Dr. Liacouras completed a pediatric gastroenterology fellowship at Children's Hospital of Philadelphia. *Id.* at 502. Since then, he has remained at Children's Hospital of Philadelphia, serving in various capacities, including director of the Gastrointestinal Endoscopy Suite, and a full professor of pediatrics and pediatric gastroenterology. *Id.* Dr. Liacouras is board certified in pediatric gastroenterology, and maintains an active medical license in the State of Pennsylvania. *Id.* at 506.

Dr. Liacouras testified that he spends 85 to 90 percent of his time seeing patients, and about 5 percent of his time conducting clinical research. Tr. at 507. Dr. Liacouras regularly treats infants with GERD and intussusception. *Id.* at 510-11. In addition, while Dr. Liacouras treats patients for a wide variety of GI, liver, and nutrition issues, he routinely diagnoses approximately 300 patients with gastroesophageal reflux each year. *Id.* at 510. He further testified that he has diagnosed roughly 100 patients with intussusception over the course of his career. *Id.* at 511.

[14] Petitioners devoted some time at hearing in an attempt to impeach Dr. Halsey as biased in favor of Respondent, based upon his prior advocacy work for an earlier iteration of a rotavirus vaccine that was no longer administered. *See generally* Tr. at 414-32. However, these efforts were largely unpersuasive. They did not diminish the probative value of the specific points from Dr. Halsey's testimony referenced herein, nor did they successfully establish grounds for doubting the veracity of Dr. Halsey's testimony overall, and therefore I do not discuss the relative merits of such attacks.

Consistent with Dr. Halsey's testimony, Dr. Liacouras maintained, based on his review of the medical evidence, that the rotavirus vaccine did not cause G.J.C. to develop intussusception. Tr. at 531; Liacouras Rep. at 4. Dr. Liacouras acknowledged that the rotavirus vaccine *can* cause an acute intussusception, but maintained that a medically appropriate timeframe to establish causation would be no more than 21 days after vaccination. Tr. at 558, 559-60. Indeed, most children experiencing an adverse reaction to the rotavirus vaccine resulting in an intussusception surgical procedure presented with symptoms within *seven* days of the vaccine's administration. Liacouras Rep. at 5. G.J.C.'s symptoms, by contrast, did not manifest until fifty-five or fifty-seven days post-vaccination. Tr. at 558-59.

As support for the above (and in addition to the Yih and Haber articles referenced by Dr. Halsey), Dr. Liacouras relied on an additional article in support of his proposed temporal interval that suggested the risk was much diminished over a longer timeframe. *See* Shui et al., *Risk of Intussusception Following Administration of a Pentavalent Rotavirus Vaccine in US Infants,* 307 JAMA 598, 598 (2012), filed as Resp't's Ex. A-19 (ECF No. 63-9) ("Shui"). Shui, a cohort study, examined the risk of intussusception following the RotaTeq vaccine in U.S. infants from May 2006-February 2010, finding no significant risk of developing intussusception following vaccination in a 1 to 30-day risk window following *any* dose. *Id.* at 598; 602.

Dr. Liacouras also maintained, based on review of the medical records, that G.J.C. had developed only a one-time, idiopathic, ileocolic acute intussusception -- not a chronic/transient series of intussusceptions with symptomatology mistakenly identified by G.J.C.'s treaters as GERD or feeding problems. Tr. at 560; Liacouras Report at 5. Although Dr. Liacouras acknowledged that some older items of literature included reference to chronic or ongoing intussusception as a medical concept, the idea did not reflect current thinking in the medical community, and had not otherwise been properly vetted since it was first proposed so as to be scientifically reliable. Tr. at 560, 603-04; Liacouras Rep. at 5. Dr. Liacouras testified that he had never seen a transient intussusception in his clinical practice (or an ileocolic intussusception that spontaneously reduced without surgical intervention). Tr. at 604, 576.

In so maintaining, Dr. Liacouras stressed the importance of the precise location in the bowel of the intussusception. Tr. at 579. While Dr. Liacouras agreed that transient/chronic small-bowel to small-bowel intussusception could exist in theory, he maintained that an *ileocolic* intussusception generally (which he proposed could not be lumped into the overall category "small bowel," given its distinct location) would *not* be transient (and in fact would only be discovered after disclosure of symptoms so acute that they led parents to seek emergency treatment). *Id.* at 524, 528, 530-31. Accordingly, he dismissed literature cited by the Petitioners discussing small-bowel to small-bowel intussusception as not only dated but irrelevant. Tr. at 565-67. An ileocolic intussusception would usually be diagnosed within hours to a day, and would present no symptoms

prior to that timeframe. *Id.* at 529-30. That did not happen here in a period close in time to G.J.C.'s receipt of either dose of the rotavirus vaccine. *Id.* at 532.

Dr. Liacouras agreed with G.J.C.'s GERD diagnosis, but questioned Dr. Santoro's opinion that these symptoms were misdiagnosed, instead constituting evidence of an ongoing transient intussusception. Tr. at 575; Liacouras Rep. at 3, 5. Based upon his review of the medical records, Dr. Liacouras opined that G.J.C. developed reflux and a herpangia infection after his first rotavirus vaccination, was treated with Prilosec for reflux, and then developed an unrelated intussusception that resolved after surgery. Tr. at 593. Dr. Liacouras allowed for the fact that G.J.C.'s GERD and intussusception resolved around the same time, but maintained that G.J.C. simply developed two conditions that were ultimately unrelated. *Id.* at 593-54. He also took issue with Dr. Santoro's suggestion that the failure of efforts to treat G.J.C.'s GERD evidenced that the symptoms were reflective of something more serious, opining instead (and based upon his specialized experience as a pediatric gastroenterologist) that G.J.C.'s treaters had not (at least in the January-April timeframe) given him a high enough dosage of Prilosec to be effective. *Id.* at 547-48, 589-90.

IV. Procedural History

Shannon and Kyle Carda filed their Petition on March 6, 2014. Pet. at 1. After gathering affidavits and various relevant medical records, Petitioners filed such materials and then their statement of completion on April 18, 2014. ECF No. 8. Respondent thereafter filed his Rule 4(c) Report on June 4, 2014, indicating his view that Petitioners were not entitled to compensation because G.J.C.'s vaccinations could not be linked to onset of his actual intussusception 56 days later. ECF No. 9.

Petitioners filed an expert report from Dr. Santoro on December 16, 2014, after obtaining extensions of time in which to act. ECF No. 15. Respondent then filed his own expert report in response on April 9, 2015, from Dr. Halsey. ECF No. 18. On June 25, 2015, Petitioners also filed a supplemental expert report from Dr. Santoro (ECF No. 23), and Respondent filed a supplemental expert report from Dr. Halsey on August 31, 2015. ECF No. 26. I subsequently allowed Petitioners the opportunity to obtain and file an additional expert report focusing on the immunological issues in this matter, which they attempted to do with Dr. Shoenfeld's report filed on November 3, 2015. ECF No. 28. Respondent filed a responsive expert report from Dr. Liacouras on January 8, 2016. ECF No. 31.

After the filing of these expert reports, I set the matter for hearing on January 24-25, 2017. ECF No. 34. The parties also agreed to the dismissal of Petitioners' Table claim, which I effected

on May 24, 2016. ECF No. 37. Respondent thereafter also filed an additional expert report from Dr. Halsey on August 8, 2016. ECF No. 43.

The parties filed pre-hearing submissions from November to December of 2016 (ECF No. 49-52), and the hearing went forward as scheduled. The parties elected to file post-hearing briefs, doing so by June 6, 2017. ECF Nos. 84, 88-89. This matter is now ripe for adjudication.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that she suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that her illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[15] In this case, the Petitioners dismissed their Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions;

[15] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *appeal docketed*, No. 2015-5097 (Fed. Cir. June 19, 2015). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[16]

[16] There is ample contrary authority for the more straightforward proposition that the first *Althen* prong, like the overall test itself, simply applies a preponderance standard when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). For purposes of the present analysis, I am stressing those cases focusing on the *plausibility* of the causal theory proposed, as opposed to whether preponderant evidence supports it, in order to avoid imposing on Petitioners a greater evidentiary burden than the law requires. This does not, however, change the fact that *any* theory's plausibility, for purposes of satisfying the *Althen* test, is properly analyzed by subjecting its components to the *Daubert* tests for scientific reliability. *Terran v. Sec'y of Health & Human Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012),

aff'd mem., 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (*i.e*., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act"). It is in the exercise of my duties as a special master to weigh competing expert testimony. *Copenhaver v. Sec'y of Health & Human Servs.*, No. 13-1002V, 2016 WL 6947389, at *5 (Fed. Cl. Oct. 20, 2016) ("Special Masters may use their discretion in weighing expert testimony, and case law supports that discretion").

In determining whether a particular expert's testimony was reliable or credible, I may consider whether the expert offers an opinion that exceeds his training or competence. *Walton v.*

Sec'y of Health & Human Servs., No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). While (in keeping with the liberality with which evidence offered in Vaccine Program cases is treated) I heard and have considered all of the testimony of the experts offered at the entitlement hearing, I may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See, e.g.*, *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, including some articles (such as those discussing molecular mimicry and protein sequences in vaccines) that do not factor into the outcome of this decision. I have reviewed all of the medical literature submitted in this case, but I only discuss those articles that are most relevant to my determination and/or are central to Petitioners' case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to — and likely undermines — the conclusion that it was not considered").

ANALYSIS

I. Overview of Intussusception

Intussusception is formally defined as the invagination, or telescoping, of one segment of the intestine within another, resulting in a bowel obstruction or ischemia. Jiang et al., *Childhood Intussusception: A Literature Review*, 8 PlosOne E68482 (2013), filed as Resp't's Ex. A.10 (ECF No. 62-10) ("Jiang"); CDC, *Addition of History of Intussusception as a Contraindication for Rotavirus Vaccination* 1 (2011), filed as Ex. 12-3 (ECF No. 70-3). It is the most common cause of bowel obstruction in infants, typically occurring in children between four and ten years old. Jiang at 1. In children, the first sign of intussusception is usually loud crying caused by acute abdominal

pain.[17] Infants may also pull their knees to their chest during crying episodes, indicating abdominal pain associated with intussusception. *Id.* Symptoms can include stool mixed with blood and mucus, vomiting, lethargy, diarrhea, fever, and lumps in the abdomen. *Id.*

The cause of intussusception is unknown.[18] However, some factors that produce an intussusception shed light on what might precipitate it. Relevant literature suggests that an intussusception can result from a viral syndrome or infection. Mary L. Brandt, *Intussusception*, *Oski's Pediatrics* (4th ed. 2006), filed as Resp't's Ex. A-2 (ECF No. 62-2). Idiopathic intussusceptions, specifically, result from enlarged lymphoid tissue, further supporting a viral cause. *Id.* Generally, viral symptoms associated with intussusception include hyperplasia of lymphoid tissue or swelling of the intestinal wall. Minney-Smith et al., *Intussusception Is Associated with the Detection of Adenovirus C, Enterovirus B and Rotavirus in a Rotavirus Vaccinated Population*, 61 J. Clin. Virology 579, 579-80 (2014), filed as Resp't's Ex. A-11 (ECF No. 63-1). It has been suggested that an intestinal invagination, or intussusception, can be triggered by post-infection hyperplasia in the gastrointestinal tract, following the rotavirus for example, and generally occurs within twenty-one days after the initial rotavirus vaccination. *Id.*; *see* Yih at 506.

An intussusception is a life-threatening illness.[19] Untreated, intussusception can cause abdominal infection and internal bleeding. *Id.* Typically, an intussusception diagnosis can be made using an abdominal x-ray, upper gastrointestinal series, or a barium enema. *Id.* Treatment varies, and can include an air enema or surgical intervention. *Id.*

II. Petitioners Have Not Carried Their Burden of Proof

A. *Petitioners' Causation Theory is Unreliable*

Importantly for purposes of analysis, Petitioners' causation theory did *not* propose that RotaTeq could (whether alone or after a series of doses) cause an acute intussusception a month or more later, with no intervening symptoms. Rather, they attempted to establish that the rotavirus vaccine could cause a series of transient, almost subclinical and self-resolving intussusceptions, abetted by a second dose, then *culminating* in an acute intussusception several weeks after

[17] *Symptoms and Causes*, Mayo Clinic, http://www.mayoclinic.org/diseases-conditions/intussusception/symptoms-causes/dxc-20166963 (last visited Oct. 5, 2017).

[18] *Intussusception*, Stanford Children's Hospital, http://www.stanfordchildrens.org/en/topic/default?id=intussusception-90-P02002 (last visited Oct. 5, 2017).

[19] *See* n.18 above.

vaccination. But the evidence offered for this theory was unreliable, and Petitioners' experts were simply not persuasive in establishing it based solely on their individualized expertise.

First, Petitioners have not demonstrated with updated and reliable scientific or medical evidence that there is a recognized condition of "chronic" or transient intussusception that could later result in the commonly-understood, acute form. Petitioners' experts could not draw on identifiable, specific expertise on the topic of intussusception (either from research or clinical experience), and therefore their reports referenced literature to support this concept.[20] But the articles cited by Petitioners (which are either somewhat dated or are case studies of inherently less probative value) merely suggest that a child might inadvertently be found to have experienced a *single* intussusception that spontaneously resolved without the need for surgical intervention – and without subsequent recurrence. Mateen, for example, involved patients presenting with symptoms of intestinal obstruction, five of whom had been symptomatic for less than a day, and were diagnosed with an intussusception that resolved on its own – *not* with a chronic, ongoing condition that later manifested as an acute condition. Mateen at 413. Steffen was a single-patient case report involving an intussusception diagnosis following four weeks of intermittent abdominal pain. Steffen at 4981. No literature was offered demonstrating an instance in which transient intussusception was identified, and then later culminated in an acute event.

Respondent's experts, by contrast, persuasively established (based upon both their particular expertise as well as the literature marshalled in this case) that at best, a "transient" intussusception was one that was incidentally discovered as having spontaneously resolved – not an ongoing condition with symptoms that might be confused with GERD or other common infant feeding issues. Respondent also effectively demonstrated that the ileocolic region of the intestine is distinguishable, for present purposes, from the small bowel, and thus was even *less* likely the location of the kind of chronic or ongoing intussusception urged by Petitioners. Petitioners' own literature discussing the concept of recurring intussusception acknowledges this distinction – as well as the greater concept that the "transience" of any such intussusception is also a measure of its insignificance. *See, e.g.,* Strouse et al., *Transient Small-Bowel Intussusception in Children on CT*, 33 Pediatr. Radiol. 316, 316, filed as Ex. 12-20 (ECF No. 70-20) (excluding ileocolic intussusceptions from review study of small-bowel intussusceptions), 320 ("the majority of small bowel intussusceptions identified on CT are transient and of little or no clinical significance"); Kim, *U.S. Features of Transient Small Bowel Intussusception in Pediatric Patients*, 5 Korean J. Radiol. 178, 178-84 (2004), filed as Ex. 12-21 (ECF No. 70-21), at 178 (distinguishing between ilecolic and small bowel intussusception).

[20] I am aware that claimants are not *compelled* to offer literature to support a causation theory, and therefore I cannot require such proof. But as noted, Petitioners *did* offer literature, and it is evident after hearing their experts that the experts lacked sufficient individual expertise to fill in an evidentiary hole that would have been left had such literature not been offered. Accordingly, it is reasonable for me to evaluate the probative value of the offered literature.

This raises the second deficiency in Petitioners' theory. Even if the Petitioners had established, with reference to persuasive and reliable evidence, the existence of a chronic/transient form of intussusception that could later produce an acute intussusception, they have not reliably established that the rotavirus vaccine could, when administered in series as herein, *cause* a transient or chronic subclinical intussusception in the first place.[21] *Nothing* was offered to establish that RotaTeq (or any other vaccine for that matter) could cause a child to experience recurring or transient intussusceptions. The manner in which the rotavirus causes an acute intussusception, as discussed above, also bears on its capacity, in vaccine form, to cause the kind of ongoing intussusception envisioned by Petitioners. As Respondent's experts persuasively established, the impact of the viral infection is understood to be sudden and severe – *not* persistent over time to a sufficient degree to maintain an undercurrent intussusception.

Petitioners' experts were unable to fill this evidentiary gap with reliable testimony drawn from their own experience in research or treatment. Dr. Shoenfeld, Petitioners' immunologist,[22] relied on concepts (challenge-rechallenge, for example) that have not been demonstrated to be relevant to the kind of live vaccine at issue, and he otherwise seemed to invoke mechanistic models (for example, the idea that vaccines can spark, via inflammation, a persistent, ongoing immune response) that facially are inapposite (given his admission that intussusception has *not* been shown by science to be autoimmune in nature). Tr. at 245. He also demonstrated no specific knowledge pertinent to the nature of G.J.C.'s illness or the RotaTeq vaccine to imbue his opinions with any added heft.

The assumption of Petitioners' theory seems to have been that if the rotavirus vaccine is known to cause acute intussusception, it reasonably could also potentially cause a chronic intussusception. But the evidence offered failed to establish this by a preponderance.

B. *Petitioners Have Not Demonstrated that G.J.C. Suffered from a Transient or Chronic Intussusception Prior to his May 2013 Surgical Procedure*

Parallel to their inability to establish that a child *could* suffer from a series of chronic, subacute intussusceptions, the Cardas were unsuccessful in demonstrating that G.J.C.'s symptoms

[21] By Dr. Shoenfeld's admission, intussusception is *not understood* to be autoimmune, so arguments often advanced in the Program about insidious autoimmune processes, producing chronic inflammation over time in a progressive or smoldering fashion, cannot be invoked herein as analogous to the course of symptoms G.J.C. experienced.

[22] I discount opinions offered in this case by Dr. Santoro on the RotaTeq vaccine's alleged causal connection to a transient intussusception, not only because of Dr. Shoenfeld's comparatively superior expertise on immunologic matters, but also because Dr. Santoro's own background as a gastroenterologist did not extend to such topics.

prior to his May 2013 intussusception procedure actually reflected a series of less severe intussusceptions. Rather, the existing medical record best supports the conclusion that from January 2013 until the intussusception requiring medical intervention, G.J.C. suffered from intermittent GERD and related gastrointestinal symptoms that (however alarming the Cardas reasonably found them to be) were *not* reflective of a chronic intussusception or something more insidious. The record does not allow me to propose an etiology for those symptoms[23], but it better supports Dr. Liacouras's opinion that G.J.C.'s GERD was distinct from his later intussusception – *not* that the former was a precursor of the latter or some lesser version of it.

Several evidentiary factors support this determination. No treaters ever proposed that G.J.C. was experiencing the kind of chronic intussusception Petitioners maintain he experienced. G.J.C.'s overall course is instead more reasonably characterized (a reflected in the record evidence) as intermittent feeding and GERD problems, with nothing so serious as to require medical intervention until the second half of May, and nothing resembling the kind of acute reaction consistent with intussusception as it is most commonly understood to manifest, let alone the far less well-supported chronic intussusception diagnosis urged by Petitioners. It is speculative to suggest, as Petitioners do, that symptoms that are congruent with *some* intussusception symptoms, but that do not result in the acute distress associated with an intussusception requiring surgical intervention should be read to reflect a chronic form of intussusception. To hijack Dr. Santoro's "horse vs. zebra" analogy, the existing medical record may have been filled with the sound of hoof beats, but it lacks anything suggestive of a stripe.

In addition, although the medical records establish that the Cardas were dutiful in their care of G.J.C., they do not corroborate their after-the-fact assertions that his feeding problems were as severe or alarming as they testified to during the hearing. It is well established in the Vaccine Program that contemporaneous medical records created at the time of the events they describe are presumed accurate and complete. *See Cucuras*, 993 F.3d at 1528 ("[O]ral testimony in conflict with contemporaneous documentary evidence deserves little weight"); *Murphy*, 23 Cl. Ct. at 733 (citing *United States v. Gypsum Co.*, 333 U.S. 364, 396 (1947)); *Lowrie*, 2005 WL 6117475, at *19. It is true that G.J.C.'s feeding issues did not resolve in this period and/or recurred, but Dr. Liacouras persuasively established that G.J.C.'s medical providers may simply not have gotten the treatments (for example, the Prilosec dosage) exactly right. Tr. at 547-48, 589-90. Dr. Liacouras also convincingly established that even if there is such a thing as a serial, transient small bowel

[23] As noted above, there is evidence that G.J.C.'s herpangina could have been the actual precursor cause for his intussusception (Tr. at 593), although there is not sufficient support in the medical record (for example, a treater's embracing of this explanation) for me to conclude it to be "more likely than not." In any event, Petitioners are arguing *not* that either vaccine was the *direct* cause of the surgical intussusception, but instead that the RotaTeq doses G.J.C. received caused a more mild, transient intussusception that later manifested in the May 2013 surgery. And it cannot be disputed that G.J.C. received his first dose of the vaccine long before the herpangina diagnosis.

intussusception, the specific location in which G.J.C.'s acute intussusception occurred (ileocolic region) rendered his condition distinguishable.

In finding as I do, I am giving greater weight to the testimony of Respondent's gastroenterologic expert, Dr. Liacouras, than that provided by Dr. Santoro. But I am empowered to do so, concurrent with the need to make credibility determinations in assessing the probative value of witness testimony in a Vaccine Program case. *See Porter*, 663 F.3d at 1250 ("[T]his court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act."); *Copenhaver*, 2016 WL 6947389, at *5 ("Special Masters may use their discretion in weighing expert testimony, and case law supports that discretion."). Dr. Liacouras demonstrated a high degree of facility and expertise with pediatric gastroenterologic matters, rendering his testimony on these matters far more compelling than Dr. Santoro (whose expertise on the topic specifically at issue was more general), and I have reasonably relied on my impressions of his greater credibility and persuasiveness in so finding.

C. *The Timeframe Between G.J.C.'s Receipt of RotaTeq Doses and his Intussusception Has Not Been Demonstrated to be Medically Acceptable*

The most reliable medical literature offered in this case establishes a short temporal connection between acute intussusception and vaccine administration. *See, e.g.*, Yih at 506. There is no medically acceptable timeframe suggesting an intussusception following a rotavirus vaccination would occur more than 21 days post-vaccination. This is consistent with the timeframe allowed for by the Table claim (*see* 42 C.F.R. § 100.3 (2017)), which is grounded in the scientific observation of *how* the RotaTeq vaccine would cause the condition. *Id.* As Dr. Halsey explained, the response to receipt of the live strains of rotavirus contained in RotaTeq would inherently be fairly sudden, and would not be subject to the kind of rechallenge response that characterizes different kinds of vaccines. Tr. at 393, 400-01, 405.

Because of the foregoing, the date G.J.C.'s intussusception was first observed by his treaters (two months from his *second* vaccination) is too attenuated from the vaccine's administration to constitute a persuasive temporal relationship. The period between when G.J.C. first received RotaTeq (January) and his May intussusception is even less defensible as medically reasonable, at least based on existing reliable science. Such timing conclusions are consistent with the most reliable evidence offered in this case. *See, e.g.*, Murphy at 564; Haber at 4873.

Nothing argued by Petitioners' experts was sufficiently reliable or persuasive to overcome the above. They offered little in the way of reliable scientific or medical evidence suggesting what timing would even be expected between vaccination and the beginning of a series of chronic

intussusceptions. And as already noted, their timing theory relied heavily on the determination that there *is* such a thing as vaccine-induced transient or chronic intussusception that can precede an acute intussusception – so my findings above largely preempt the need to consider if the timing shown herein is medically acceptable. But the arguments Petitioners' experts otherwise made were substantively weak. Dr. Shoenfeld, for example, maintained that periods even *more* lengthy than relevant herein were still plausible, despite his reliance on mechanisms (for example, ongoing autoimmune reactions) that do not bear on the injury in question. Tr. at 295-97.

The deficiencies in such arguments are highlighted when measured against the total timeframe for the period relevant to this case. Approximately ***nine weeks*** passed between the first and second doses of RotaTeq, with no reported reaction other than the aforementioned GERD and feeding issues, none of which resulted in hospitalization or a level of intervention comparable to what G.J.C. later experienced. Thereafter, an additional ***eight weeks*** passed from the second dose to G.J.C.'s intussusception requiring surgery on May 22nd. Petitioners have not established with credible, persuasive evidence that it is reasonable to conclude that such long time periods are acceptable timeframes in which a transient/chronic intussusception would fester, later resulting in an acute intussusception.

In many respects, it appears Petitioners have attempted to shoehorn a timeframe theory into the chronology relevant to G.J.C.'s history, characterized as it is by long periods of mild symptoms not deemed significant by treaters, rather than the acute incidents associated with intussusception as it is best understood. *See, e.g.,* Tr. at 312-13. But such ends-based reasoning relies too heavily on the temporal relationship between G.J.C.'s vaccinations and his later intussusception, and is clearly rejected by relevant case law. *See, e.g., U.S. Steel Group v. United States*, 96 F.3d 1352, 1358 (Fed. Cir. 1996) ("But to claim that the temporal link between these events proves that they are causally related is simply to repeat the ancient fallacy: post hoc ergo propter hoc"); *Fricano v. United States*, 22 Cl. Ct. 76, 80 (1991) ("[P]ost hoc ergo propter hoc . . . is regarded as neither good logic nor good law"); *Doe/34 v. Sec'y of Health & Human Servs*., 2009 WL 1955140, at *10 (Fed. Cl. Spec. Mstr. Mar. 4, 2009); *Pafford v. Sec'y of Health and Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *9 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006).

D. *Petitioners Have Not Carried Their Burden of Proof.*

Because of the above findings, I find that Petitioners have offered insufficient preponderant evidence in support of the three *Althen* prongs.

Regarding the first, "can cause" *Althen* prong, Petitioners have failed to establish that the RotaTeq vaccine can cause a chronic/transient series of intussusceptions that over time manifest

into a single acute incident akin to the kind of injury included in the Table version of such a claim. They offered insufficient, up-to-date, reliable scientific or medical evidence supporting the conclusion that there *is* some form of transient intussusception, let alone a chronic condition that is vaccine-induced. Their reliance on VAERS-style data to support the proposed connection is unpersuasive, as observed in other cases. *See, e.g., Vig v. Sec'y of Health & Human Servs.*, No. 01-198V, 2013 WL 6596683, at *17 (Fed. Cl. Spec. Mstr. Nov. 14, 2013) ("VAERS is a stocked pond, containing only reports of adverse events after vaccinations but no data about the number of vaccines administered or the occurrence of the same adverse event in individuals who have not been vaccinated. Thus, the information in the VAERS report is meaningless without this additional data") (internal quotations omitted)). And neither of Petitioners' experts had sufficient direct experience with the relevant vaccine or injury at issue to fill evidentiary holes with their own personal observations or opinions on the subject.

Next, Petitioners have not offered sufficient preponderant evidence on the second *Althen* prong to permit the conclusion that the RotaTeq vaccine likely caused G.J.C.'s May 2013 intussusception, by initiating a series of chronic intussusceptions culminating in a more acute event. Rather, the evidence (supported by Dr. Liacouras's persuasive testimony) supports the determination that G.J.C.'s ongoing GERD and feeding issues were just that – concerning but not acute, and not evidence of the mild, chronic form of intussusception that Petitioners argue exists. Certainly no treater ever associated G.J.C.'s symptoms as chronic intussusception. I also see nothing in the record that suggests G.J.C. experienced a vaccine reaction *of any kind*. To the extent the Petitioners hoped to vary the contemporaneous medical records with their own statements about the severity of G.J.C.'s alleged vaccine reaction, they have not succeeded in doing so.

Finally, Petitioners were unsuccessful in establishing that the timeframe between G.J.C.'s vaccinations and his acute intussusception was medically appropriate for causation. Far too much time passed between the second RotaTeq dose and the May 2013 intussusception to conclude there is an acceptable causal relationship, and Petitioners could not demonstrate reliable medical or scientific support (beyond offering limited case studies or more VAERS data) supporting the reasonableness of such timeframes. The most reliable evidence suggests the rotavirus vaccine would cause intussusception quickly – not seven or eight weeks later – and the arguments marshalled by Dr. Shoenfeld against this conclusion relied on circumstances inapposite to this case and the nature of the relevant injury. Petitioners also failed to establish any identifiable relationship between the first and second RotaTeq doses such that I could conclude the second's immunogenicity was enhanced consistent with the concept of "challenge-rechallenge." Rather - the most reliable evidence offered herein on this subject, such as Yih or Haber, establishes a risk only after the *first* dose of RotaTeq, and then only in a narrow temporal window. Yih at 503. That timeframe was exceeded herein.

CONCLUSION

The Vaccine Act permits me to award compensation only if a petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. The Petitioners were not successful in doing so in this case. I therefore must **DENY** this claim for compensation.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.[24]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[24] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.